REMARKS

Claims 6-7 are pending in this application. Claims 6-7 have been rejected. Claims 6 and 7 have been amended. No new matter has been added by this amendment. Applicants are respectfully requesting reconsideration in light of the amendments to the claims and the following remarks.

I. Claim Interpretation.

At page 2, ¶2 of the Office Action, the Examiner acknowledges that the term "isolated" distinguishes the claimed biological matter from its natural surroundings or environment. However, it is suggested that the term "of" is interpreted as open or "comprising" language, which allows for the inclusion of outside elements. The Examiner therefore asserts that any prior art reference disclosing a product, isolated in any matter from its natural surroundings, that necessarily contains the recited "fraction" would read on the claim.

Applicants respectfully disagree with the Examiner's interpretation of the claimed invention. It appears that the Examiner has improperly interpreted the claimed invention to describe any composition comprising the claimed isolated ultrafiltration fraction. However, MPEP §904 instructs Examiners to conduct an art search that covers "the invention as described and claimed." In this regard, the claimed invention is not any composition comprising the claimed isolated ultrafiltration fraction, rather the claimed composition is the isolated ultrafiltration fraction itself.

II. Rejection of Claims Under 35 U.S.C. 112

Claims 6-7 have been rejected under 35 U.S.C. 112, first paragraph, as failing to meet the written description requirement. At pages 3 and 4 of the Office Action the Examiner asserts:

> In the instant case, the claimed invention encompass fractions of nucleic acid molecules that are not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed genus. Specifically, the specification provides no support for fractions of strictly polyA- RNA molecules greater than 400, 500, etc. nucleotides that enhance amplification Prp^{Sc}.
>
> Reduction to Practice
> The specification discloses that RNA which enhanced Prp^{Sc} amplification was determined to be greater than 300 nucleotides (pg. 7); however, there is no evidence that a fraction containing solely polyA- RNA molecules greater 400, 500, etc. nucleotides would enhance Prp^{Sc} amplification. Also, the specification provides no experimental evidence of even one molecular sequence structure thought to have "enhancement" properties.
>
> Reduction to Drawing
> The specification provides no written sequence structure of even one RNA molecule thought to have "enhancement" properties.
>
> Disclosure of Relevant Identifying Characteristics
> While one could argue that a skilled artisan would be able to identify the specific RNA molecules having such "enhancement" properties through "routine" methods known within the art (e.g. SELEX), such methods would not satisfy the written description for the genus claims when the claims require an essential or critical feature(s), adequately described in the

> specification, when the feature(s) is not conventional in the art or known to one of ordinary skill in the art (MPEP 2163). For the claims at hand, an example of an essential or critical feature is the RNA sequence structure essential for the "enhancement" property. For example, the specification recites, "The RNA molecule may be the entire RNA molecule or an active fragment thereof which retains the capacity for enhancing the amplification of Prpsc (pg. 10);" however, the sequence of such an active fragment was not elucidated.

Applicants respectfully disagree and traverse this rejection. While the Examiner asserts that "the specification provides no support for fractions of strictly polyA- RNA molecules greater than 400, 500, etc. nucleotides that enhance amplification Prp^{sc}" and "there is no evidence that a fraction containing solely polyA- RNA molecules greater 400, 500, etc. nucleotides would enhance Prp^{sc}," Applicants respectfully submit that there are no such limitations recited in the instant claims. In particular, the claims do not require a fraction containing solely polyA- RNA, rather the claims require ribonucleic acid molecules that do not bind to an oligo dT column. Secondly, the claims do not require fractions containing RNA molecules greater than 400, 500, etc. nucleotides, rather the claims require ribonucleic acid molecules of >300 nucleotides.

The purpose of the written description requirement under 35 U.S.C. § 112, first paragraph is to convey with reasonable clarity to those skill in the art, that, as of the filing date sought, appellants were in possession of the invention now claimed. *Vas-Cath Inc. v. Makurar*, 935 F.2d 1555, 1564, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991). In this regard, one cannot

describe what is not claimed, nor is there any requirement under 35 U.S.C. 112, first paragraph, to do so.

Applicants claim is to an isolated ultrafiltration fraction containing ribonucleic acid molecules of >300 nucleotides, which do not bind to an oligo dT column and enhance the amplification of PrP^{Sc}. In this respect, Applicants describe the isolation of RNA from brain tissue and demonstrate that this isolated RNA enhances amplification of PrP^{Sc} (see page 6, lines 25-30). Applicants further fractionate the isolated RNA by ultrafiltration and demonstrate that the filter retentate, *i.e.*, RNA molecules >300 nucleotides, are responsible for catalyzing PrP^{Sc} conversion (see page 7, first full paragraph). Applicants subsequently demonstrate that enhanced amplification of PrP^{Sc} is attributed to RNA molecules that do not bind to an oligo dT column (see page 7, first full paragraph). In so far as the skilled artisan would have been familiar with ultrafiltration, oligo dT column chromatography and methods for assessing PrP^{Sc} conversion, the specification described the claimed invention in such terms that those skill in the art would understand that Applicants were in possession of the invention now claimed. As such, the written description requirement of 35 U.S.C. §112, first paragraph, has been met.

Furthermore, Applicants respectfully disagree with the Examiner's requirement that the specification provide sequence structure of an RNA molecule thought to have 'enhancement' properties. "Compliance with the written description requirement is essentially a fact-based inquiry that will 'necessarily vary depending on the nature of the invention claimed.'" *Enzo*

Biochem, 323 F.3d at 963, 63 USPQ2d at 1613. An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997). Indeed, one way of showing possession is by describing distinguishing identifying characteristics of the claimed invention. See, *e.g.*, *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 68, 119 S.Ct. 304, 312, 48 USPQ2d 1641, 1647 (1998); *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406; *Amgen, Inc. v. Chugai Pharmaceutical*, 927 F.2d 1200, 1206, 18 USPQ2d 1016, 1021 (Fed. Cir. 1991) (one must define a compound by "whatever characteristics sufficiently distinguish it"). In this respect, Applicants distinguish their invention by describing the composition as being an isolated ultrafiltration fraction of >300 nucleotide ribonucleic acid molecules, which do not bind to an oligo dT column and enhance the amplification of PrP^{Sc}.

Accordingly, while the Examiner has rejected the instant claims under 35 U.S.C., first paragraph, based upon overly stringent criteria and upon limitations not expressly recited in the claims, the Examiner has not provided any evidence or reasonable basis to challenge the adequacy of the written description for the claims as currently presented. In view of the foregoing, Applicants respectfully submit that the one skilled in the art would reasonably conclude that Applicants had possession of the invention now claimed. It is therefore respectfully requested that this rejection be withdrawn.

III. Rejection of Claims Under 35 U.S.C. 102

Claim 6 has been rejected under 35 U.S.C. 102(b) as being anticipated by Saborio et al. ((2001) *Nature* 411:810-3). The Examiner contends that this reference teaches a composition comprising a fraction of polyA- RNA molecules greater than 300 nucleotides that enhances the amplification of PrP^{Sc}, asserting that healthy hamster brain homogenate necessarily "comprises" a fraction of polyA- RNA greater than 300 nucleotides that enhance the amplification of PrP^{Sc}.

Applicants respectfully traverse this rejection. As indicated herein, Applicants respectfully submit that the Examiner has improperly interpreted the present invention as a composition comprising an isolated ultrafiltration fraction, rather the isolated ultrafiltration fraction itself. In this respect, while Saborio et al. teach total hamster brain homogenate, this reference does not teach or suggest an isolated ultrafiltration fraction as claimed.

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). See MPEP 2131.

In so far as Saborio et al. teach total hamster brain homogenate, this reference does not teach the isolated ultrafiltration fraction as presently claimed and therefore cannot be held to anticipate the present invention. It is therefore respectfully requested that this rejection be withdrawn.

Claim 6 has been rejected under 35 U.S.C. 102(b) as being anticipated by Mizutani et al. ((2000) *Virology* 275:238-43). It is suggested that this reference teaches the isolation of mouse polyA- RNA molecules from total RNA and subsequent gel separation. The Examiner contends that the combination of gel fractions of Mizutani et al. containing RNA molecules greater than 300 nucleotides necessarily enhances the amplification of PrP^{Sc}.

Applicants respectfully disagree with this rejection. Applicants have demonstrated that the isolation and fractionation of RNA from brain tissue enhances amplification of PrP^{Sc} (see page 6, lines 25-30). While Mizutani et al. teach an RNA fraction from cells infected with MHV, wherein said fraction does not bind to the oligo-dT cellulose (col. 1 and 2 at page 239), this reference does not teach or suggest fractionation of RNA from brain tissue. Therefore, in an earnest effort to facilitate the prosecution of this application, Applicants have distinguished the present invention by amending claim 6 to indicate that the RNA is from brain tissue. Support for this amendment is found at page 6, lines 25-30 and Example 6 of the specification.

In so far as Mizutani et al. fail to teach or suggest each and every limitation of the invention as currently presented, it is respectfully requested that this rejection under 35 U.S.C. 102(b) be withdrawn.

IV. Rejection of Claims Under 35 U.S.C. 103

Claim 7 has been rejected under 35 U.S.C. 103(a) as being unpatentable over Saborio et al. or Mizutani et al. in view of Stratagene ("Gene Characterization Kits" 1988). It is suggested that it would have been obvious, based upon the supportive teaching of the Stratagene catalog, to combine reagents into kit format.

Applicants respectfully traverse this rejection. MPEP 2143.03 instructs:

> "If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious."

Simply stated, a claim that depends from a nonobvious independent claim is nonobvious because it contains all of the limitations of that independent claim plus a further limitation. (*Hartness Int'l. Inc. v. Simplimatic Engineering Co.*, 819 F.2d 1100 (Fed. Cir. 1987), *cited by In re Fine*, 837 F.2d 1071 (Fed. Cir. 1988), *cited by* MPEP 2143.03).

In the instant case, parent claim 6 is novel and non-obvious, and therefore claim 7, which depends therefrom, is also novel and non-obvious. Accordingly, per MPEP 2143.03, it is respectfully requested that the rejection of claim 7 be reconsidered and withdrawn.

V. Conclusion

Applicants believe that the foregoing comprises a full and complete response to the Advisory Action of record. Accordingly,

favorable reconsideration and subsequent allowance of the pending claim is earnestly solicited.

Respectfully submitted,

Jane Massey Licata
Registration No. 32,257

Date: **August 18, 2009**

Licata & Tyrrell P.C.
66 E. Main Street
Marlton, New Jersey 08053
(856) 810-1515